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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,522	03/10/2005	Shinichiro Yokoyama	MOR-254-A	5175

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EXAMINER	
MEDWAY, SCOTT J	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
03/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/527,522	YOKOYAMA ET AL.	
	Examiner	Art Unit	
	SCOTT MEDWAY	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office Action based on the 10/527522 application filed 03/10/2005. Examiner acknowledges the reply filed 11/25/2009.

Claims 1, 2 and 4 are currently pending and are considered below. Claim 1 has been amended.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (U.S. Pat. 5,135,484) in view of Ohara et al (U.S. Pat. 4,360,324, hereinafter "Ohara").

Regarding claim 1, Wright discloses a device for infusion therapy, comprising as in Fig. 3 a balloon catheter; a guide wire (56) to be inserted into a guide lumen (50) that guides the catheter body to a target position; a plurality of lumens (e.g. 60, 72) extending along an axis; heart pulsation detection means (col. 3, lines 22-25); and two expandable balloons (48) arranged in series. The plurality of lumens comprise an infusion lumen (60), which can supply a drug-like slurry to the outside of the catheter, is shown in Fig. 3 to have an infusion hole located in between the two balloons. The device comprises: balloon lumens (44) communicating with the insides of the two balloons to control expansion of the balloons; a bypass lumen (72) which is located outside of the two balloons, which contains bypass holes (e.g., 70 and the exit from lumen 72 being a hole) which allows flow (col. 4, lines 44-46); and a lumen (e.g. 56, 72)

which serves as a guide lumen to communicate with the outside of the catheter body and a bypass lumen (col. 4, lines 41-50).

Examiner notes that at least the claim language "wherein the bypass lumen is formed from the guide lumen into which the guide wire that guides the catheter body to a target position is inserted" (claim 1) recites substantial functional language. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)). See also MPEP 2114. Since Wright discloses a bypass lumen, it is Examiner's interpretation that the bypass lumen of Wright is capable of functioning without modification as a guide lumen during operation of the device, such that the bypass lumen would be "formed from" the guide lumen. Examiner additionally notes, for the benefit of Applicant, that the language "formed from" does not most clearly specify that the bypass lumen serves as the guide lumen during some portion of the device's operation, and that alternative claim language may be preferred.

It is noted that Wright does not disclose stroke means for causing the guide wire to stroke in synchronization of the pulsation of the heart. Ohara discloses a pulsatile pumping apparatus that has means which stroke in synchronization with the pulsation of the heart (col. 3, lines 517-65; col. 7, lines 11-20). Since Wright discloses the desire to permit a high level of fluid flow around a treatment zone via bypass lumen and to detect and monitor fluid flow and pressure in a vessel (col. 3, lines 22-25; col. 4, lines 54-56; col. 5, lines 25-27) and to use for instance a piston pump (col. 5, line 36) to pump

material to and from the vessel site, it would have been obvious to one of ordinary skill in the art at the time of the invention to consider adapting the flow detection system present in the device of Wright for integrating the means to control stroke of a guide wire (for instance as a pump-like store-and-release mechanism as taught by Ohara, to ensure a high level of blood flow through the bypass lumen. Examiner asserts that at some point during the procedure disclosed by Ohara, a guide wire in combination with a pump could be partially removed from a guide lumen to a position distal the bypass holes, which would allow the stroke means of Wright to perform their intended function (i.e., allowing the bypass lumen to work with the stroke means to bypass an occluded area formed by the two balloons) in the combination of Wright in view of Ohara.

It is additionally noted that Wright does not disclose the balloon catheter being previously combined with the guide wire and inserted. Since it has been held that separating into two devices a process which can alternately be performed as integral involves only routine skill in the art, one of ordinary skill in the art at the time of the invention could be motivated to combine or separate the guide wire and balloon previous to insertion as a matter of choice.

Regarding claim 2, Wright discloses the device to have a lumen (44) which inflates both of the balloons shown in Fig. 3 (col. 3, lines 1-2).

3. Claim 4 is rejected as being unpatentable over Wright (U.S. Pat. 5,135,484) in view of Ohara et al (U.S. Pat. 4,360,324), further in view of Corday et al (U.S.

Pat. 4,689,041, hereinafter "Corday") or Hall et al (U.S. Pat. 6,196,230 B1, hereinafter "Hall") or Smits (U.S. Pat. 6,549,812 B1).

It is noted that Wright discloses the use of the device in the coronary artery, it does not disclose the device for insertion into a coronary vein. The patents of Corday, Hall and Smits disclose the use of balloon catheter systems for introduction of drugs or for occlusion or removal of material from a vessel where the devices are used for insertion into a coronary vein. Accordingly, one of ordinary skill in the art at the time of the invention would be prompted to modify the combination of Wright in view of Ohara so that it can be used in the coronary vein, which is a function considered obvious in view of the conventionality of this particular intended use (e.g., for infusing material into a vessel).

Response to Arguments

4. Applicant's arguments filed 11/25/2009 have been fully considered but they are not persuasive. Applicant is directed to the above section 103 rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/
Examiner, AU 3763
02/26/2010

/Nicholas D Lucchesi/
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